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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year) 01.03.2000

Applicant's or agent's file reference
H0535/7007WO

IMPORTANT NOTIFICATION

International application No.
PCT/US99/01193

International filing date (day/month/year)
20/01/1999

Priority date (day/month/year)
20/01/1998

Applicant
GREEN, Howard et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H0535/7007WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/01193	International filing date (day/month/year) 20/01/1999	Priority date (day/month/year) 20/01/1998
International Patent Classification (IPC) or national classification and IPC C12Q1/52		
Applicant GREEN, Howard et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 13/08/1999	Date of completion of this report 01.03.2000
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Mennessier, T Telephone No. +49 89 2399 8687



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US99/01193

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

Description, pages:

1-35 as originally filed

Claims, No.:

1-76 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
☒ claims Nos. 1-52.

because:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

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- ☒ the said international application, or the said claims Nos. 1-52 (with respect to industrial applicability) relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-73
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-73
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	53-73
	No:	Claims	

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US99/01193

1). Preliminary remark

Reference is made to the following document cited in the international search report ✓

D1: US-A-5 773 577

2). Comments with regard to item III

- a) Claims 1-52 which are directed to methods of treatment of the human or animal body relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
- b) For the assessment of such claims on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

3). Comments with regard to item V

a) Novelty

None of the various aspects of the claimed invention appear to be disclosed in the relevant state of the art (see the non-intermediate document cited in the international search report). Therefore, it can be acknowledged that the claimed subject-matter as a whole is new, in accordance with the requirements of Article 33(2) PCT.

b) Inventive step

- (i) The technical problem solved by the invention may be regarded as the provision of means for attaching agents, such as a cosmetic agent, a bulking agent, a coloring agent or a pharmaceutical agent to a body tissue.
- (ii) The solutions proposed in the claims rely on the use of transglutaminase acting on a linking molecule. They appear not to be suggested in the relevant state of the art. Therefore, it can be acknowledged that the claimed subject-matter as a whole involves an inventive step, in accordance with the requirements of Article 33(3) PCT.

c) Document D1 cited as a P-Document

If it appeared that the priority were not valid document D1 should be taken into consideration when examining whether the claimed subject-matter is new and involves an inventive step.

4). Comments with regard to item VIII

- a) The expression "a non-corneocyte, nonlabeling agent" as used in claim 1 lacks clarity, contrary to article 6 PCT:
 - (i) Whereas from the description (see page 2, lines 10-14) it can be derived that it has been intended to specify that the agent to be fixed is not a corneocyte protein, the said expression does not account for this essential technical feature.
 - (ii) As according to a particular embodiment the agent can be a coloring agent (see page 5, line 3), i.e., an agent which could be used as a label, the term "nonlabeling" appears to be ambiguous.
- b) It is not clear from the description, contrary to Article 6 PCT, why the

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US99/01193

restriction introduced by the Applicants in claim 1 as regards the agent to be fixed to a body tissue, should not also apply to independent claims 20 and 32. In this respect, the mere statement on page 5, lines 24-28 is not regarded as being convincing.

- c) Each of claims 43 and 44 fails to specify the steps which are essential to the performance of the respective claimed methods. Said steps are only mentioned in dependent claim 45. Therefore, claims 43 and 44 are objected to under article 6 PCT.
- d) Also claim 53 lacks clarity, contrary to Article 6 PCT, as according to a particular embodiment mentioned in the claim the nonlabeling agent referred to therein could be a coloring agent, i.e., an agent which could serve the purpose of labeling a structure.